STATEMENT OF EMERGENCY
902 KAR 2:230E

This emergency administrative regulation is being promulgated to establish COVID-19 antibody administration centers (CAACs) throughout the Commonwealth, including protocols for appropriate patient eligibility criteria for receiving treatment and the administration of treatment. This emergency administrative regulation is needed pursuant to KRS 13A.190(1)(a)1. to protect public health, safety, and welfare, and KRS 13A.190(1)(a)3. as directed by 2021 Extra. Sess. Ky. Acts Ch. 5. This emergency administrative regulation will not be replaced by an ordinary administrative regulation.

ANDY BESHEAR, Governor
ERIC C. FRIEDLANDER, Secretary

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Epidemiology and Health Planning
(New Emergency Administrative Regulation)

902 KAR 2:230E. COVID-19 antibody administration center.

EFFECTIVE: October 1, 2021
RELATES TO: KRS 39A.350 to 39A.366, 194A.050, 211.180, 216B.015, 21 U.S.C. 360 bbb-3(b)(1)
STATUTORY AUTHORITY: 2021 Extra. Sess. Ky. Acts Ch. 5
NECESSITY, FUNCTION, CONFORMITY: 2021 Extra. Sess. Ky. Acts Ch. 5 Section 2 requires the Cabinet for Health and Family Services to assist and support established and additional COVID-19 antibody administration centers (CAACs) throughout the Commonwealth, develop protocols for appropriate patient eligibility criteria for receiving treatments, and proper protocol for the administration of treatments. 2021 Extra. Sess. Ky. Acts Ch. 5 Section 4 requires the cabinet to promulgate an emergency administrative regulation to implement Section 2. This emergency administrative regulation establishes the CAAC process, patient eligibility criteria, and treatment protocols.

Section 1. A COVID-19 antibody administration center shall abide by the most current guidance on monoclonal antibody treatment issued by the federal Food and Drug Administration available online at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs.

Section 2. (1) The Kentucky Department for Public Health shall establish a program to support, through direct financial support and other coordinating activities, CAACs for the work associated with inclusion on a state-published antibody administration website.
(2) The program established in subsection (1) of this section shall be available to all sites that agree to join this statewide network, subject to the available supply of monoclonal antibody treatments provided by the federal government through its established distribution program.

STEVEN J. STACK, MD, MBA, Commissioner
ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: September 27, 2021

FILED WITH LRC: October 1, 2021 at 10:03 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on November 22, 2021, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by November 15, 2021, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends virtually will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until November 30, 2021. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Julie Brooks or Krista Quarles

(1) Provide a brief summary of:

(a) What this administrative regulation does: This new emergency administrative regulation references the federal Food and Drug Administration guidance for monoclonal antibody administration, including patient eligibility criteria, and treatment protocols.

(b) The necessity of this administrative regulation: In order to expand the use of monoclonal antibodies to treat COVID-19 infection, the cabinet has been directed to promulgate an emergency administrative regulation regarding the establishment of CAACs throughout the fifteen (15) Area Development Districts, patient eligibility protocols, and treatment protocols.

(c) How this administrative regulation conforms to the content of the authorizing statutes: 2021 Extra. Sess. Ky. Acts Ch. 5 Section 4 requires the cabinet to promulgate an emergency administrative regulation to implement the CAAC process, patient eligibility criteria, and treatment protocols.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This new emergency administrative regulation references the most current guidance on monoclonal antibody treatment issued by the Federal Food and Drug Administration (FDA) and requires all CAACs abide by this guidance. This ensures the proper patient identification and treatment protocols for the administration of monoclonal antibodies to treat COVID-19 infection.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This is a new administrative regulation.

(b) The necessity of the amendment to this administrative regulation: This is a new administrative regulation.

(c) How the amendment conforms to the content of the authorizing statutes: This is a new administrative regulation.

(d) How the amendment will assist in the effective administration of the statutes: This is a new administrative regulation.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This new emergency administrative regulation will impact all health care providers and health facilities who identify as a CAAC.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in questions (3) will have to take to comply with this administrative regulation or amendment: All health care providers and health facilities operating a CAAC will need to abide by the requirements issued by the FDA through the emergency use authorization of monoclonal antibody.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the identities identified in question (3): The costs is unknown. Many health care providers and health facilities have sufficient equipment for the safe storage and handling of, and treatment with monoclonal antibodies. Those that do not currently have the required facilities and equipment would incur the costs associated with procuring these.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Health care providers and health facilities will be able to offer a monoclonal antibody treatment to eligible patients. This may help to slow the disease progression and ease the current strain on the hospital system in the commonwealth.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: This new emergency administrative regulation will have no impact on the budget of the cabinet. The authorized use of monoclonal antibodies has been issued by the FDA.

(b) On a continuing basis: This new emergency administrative regulation will not impact the budget of the cabinet on an ongoing basis.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The funding necessary to implement this emergency administrative regulation will be the American Rescue Plan Act as authorized by 2021 Extra. Sess. Ky. Acts Ch. 2.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new or by the change, if it is an amendment: An increase in fees or funding is not necessary to implement this new emergency administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees. This new emergency administrative regulation does not establish any fees.

(9) TIERING: Is tiering applied? Tiering is not applied. All health care providers and health facilities operating as a CAAC will need to abide by the guidance issued by the FDA.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This new emergency administrative regulation will impact the Division of Epidemiology and Health Planning in the Department for Public Health.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. 2021 Extra. Sess. Ky. Acts Ch. 5

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This new emergency administrative regulation does not generate revenue.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This new emergency administrative regulation does not generate revenue.

(c) How much will it cost to administer this program for the first year? There is no cost associated with this new emergency administrative regulation.

(d) How much will it cost to administer this program for subsequent years? There is no cost associated with the new emergency administrative regulation.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation: